

REMARKS

It is noted with appreciation that claims 9-11 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Accordingly, dependent claims 9 and 10 are rewritten in independent form, but with a slight clarification in claim 9. In particular, after "a metering pocket" copied from claim 1, the phrase "with powder loaded into said metering pocket" is not copied into claim 9 since the loading of the metering pocket is recited later in claim 9. Claim 11 depends from claim 10. Claims 9-11 are now allowable.

Claim 12, which is directed to the megadose disc embodiment of FIGS. 8 and 9 has been rewritten in independent form, but with the addition of "a mechanism for sequentially presenting said metering pockets to the location of a jet."

New claims 14-21 are presented.

Favorable reconsideration of the application in its presently-amended form is requested.

Claim 1

Claim 1 stands rejected under 35 USC §102 as anticipated by either Riggs et al Pat. No. 5,186,166 or Gerde Pat. No. 6,003,512. Reconsideration is requested.

Of these two references, Gerde, particularly the embodiment of Gerde FIG. 7, is the more relevant, and accordingly is discussed first below.

The disclosure of Gerde, however, differs from the claimed invention in that the Gerde "powder chamber 12" is not a metering pocket as in applicant's claim 1. In particular, the Gerde powder chamber 12 is not filled with powder. Therefore, Gerde does not disclose a "metering pocket" as claimed. In

applicants' embodiments, the pocket acts as a measuring device, which determines the amount of powder to be fluidized.

Gerde does not disclose applicant's invention of claim 1 in the identical manner required to support a rejection for anticipation under 35 USC §102, nor does Gerde suggest the invention within the meaning of 35 USC §103.

The disclosure of Riggs et al is far less relevant. Riggs et al discloses a conical reservoir 72. There is no disclosure or suggestion whatsoever that the Riggs et al reservoir 72 serves as a metering pocket.

Accordingly, claim 1 is allowable.

Claim 2

Claim 2 stands rejected under 35 USC §103 as unpatentable over Gerde. The Examiner asserts that "to have made the pocket of Gerde in the claimed size would have been merely an obvious alternative design choice known to one skilled in the art as it was known that under certain conditions extremely small doses are necessary and therefore the size of the pocket holding these small doses could indeed be made within the claimed size range."

To the contrary, fundamentally Gerde does not disclose a "metering pocket" as in claim 1, from which claim 2 depends. Gerde FIGS. 8-11 illustrate various alternatives for powder supply; in none of these does the powder chamber (which itself is of constant size) serve as a metering pocket. Indeed, Gerde column 10, lines 33-34, refers to increasing the amount loaded "from 0.05 to 0.5 mg," without changing the size of the powder chamber itself. Gerde column 10, lines 43-44 refers to "a 0.3 mL powder chamber." 0.3 mL is approximately $0.3 \text{ cm}^3 = 300 \text{ mm}^3$, or 300 times as large as the micropocket metering pocket of applicant's claim 2. There is no suggestion

in Gerde of employing a micropocket metering pocket "having a volume of the order of one cubic millimeter." Moreover, such is directly contrary to the Gerde disclosure wherein different powder amounts may be loaded into the powder chamber.

Accordingly, claim 2 is allowable on the basis of its own recitations, as well as for dependency from allowable claim 1.

Claim 3

Claim 3 stands rejected under 35 USC §102 as anticipated by either Riggs et al or Gerde. There is no indication that Riggs et al employs a gas jet at a velocity approaching Mach 1. Although Gerde does not state any particular velocity, it is possible that the Gerde apparatus does employ such a high velocity. Claim 3 is allowable at least for the reason that claim 3 depends from allowable claim 1.

Claim 4

Claim 4 is allowable at least for the reason that it depends from allowable claim 1.

Claim 5

Claim 5 recites that the jet directs gas continuously into the metering pocket, and stands rejected under 35 USC §102 as anticipated by either Riggs et al or Gerde. Riggs et al apparently discloses a continuous gas jet, but there is no "metering pocket" as claimed. Gerde directs gas impulsively, not continuously, and accordingly is not applicable to claim 5. Accordingly, claim 5 is allowable for its own recitations, as well as for its dependency from allowable claim 1.

Claim 6

Claim 6 recites that the jet directs gas both continuously and impulsively into the metering pocket, and stands rejected under 35 USC §102 as anticipated by either Riggs et al or Gerde. There is no such disclosure or suggestion in either Riggs et al or Gerde. The rejection of Claim 6 is unsupported. Claim 6 distinguishes over the prior art on the basis of its own recitations, as well as for dependency from allowable claim 1.

Claims 7 and 8

Claims 7 and 8 are allowable at least on the basis they depend from allowable claim 1.

Claims 9-11

Claims 9-11 were indicated as allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Dependent claims 9 and 10 are now rewritten in independent form, but with a slight clarification to the language of claim 9 as noted above on page 9 in the first paragraph under the heading "Remarks."

Claim 12

Claim 12 stands rejected under 35 USC §102 as anticipated by Gerde. Claim 12 is directed to the megadose disc embodiment of applicant's FIGS. 8 and 9, and discussed in specification paragraphs numbered [0084] through [0093] as filed ([0088] through [0097] as published). Claim 12 calls for "a megadose disc having a surface and a plurality of metering pockets formed in said surface." There is no such disclosure or suggestion in Gerde, and the Examiner has pointed to no such suggestion.

Additionally, claim 12 is amended into independent form, with the additional recitation of "a mechanism for sequentially presenting said metering pockets to the location of a jet" as disclosed in the specification. The specification further discusses the characteristics and advantages of this structure, which is far removed from the disclosure of Gerde.

Accordingly, the rejection of claim 12 is unsupported, and claim 12 is allowable.

Claim 13

Claim 13 stands rejected under 35 USC §102 as anticipated by Hammarlund U.S. Patent No. 5,711,292. Reconsideration is requested.

Claim 13 is directed to an aerosol generator including "an atomizer" which atomizes "a liquid solution of an active ingredient and a volatile solvent." The solution is atomized to produce droplets from which the solvent evaporates to leave an expansive bolus of solute residue. As noted in specification paragraph [0096] as filed ([0100] as published), a significant advantage of the atomized liquid embodiment of FIG. 10 is that aerosols are manufactured within the aerosol generator 102, avoiding the difficulties and expenses of separately manufacturing and handling bulk powders.

The device disclosed in Hammarlund differs significantly, in that the volatile solvent, when employed, does not evaporate, at least not fully. Thus, Hammarlund employs the term "aerosol" in the sense of fine droplets of a liquid. Indeed, as disclosed in Hammarlund column 2, line 35, the liquid which is delivered to the container "may be purely a medicine."

There is no disclosure or suggestion in Hammarlund of "an atomizer for atomizing the solution to produce droplets from

which solvent evaporates to leave an expansive bolus of a solute residue" as claimed.

Claim 13 is accordingly allowable.

New Claims 14-21

A significant aspect of applicant's invention is the provision of an aerosol generator which produces an aerosolized powder transported by a gas flow at a predictable average mass flow rate, as discussed at various points in the specification, such as paragraph [0046] of the application as filed ([0051] as published) and paragraph [0083] as filed ([0087] as published). Related to that, specification paragraph [0090] as filed ([0094] as published) discloses the manner in which the mixing chamber (which may also be termed a mixing/stilling/classification chamber) stills and mixes each new bolus delivered with boli delivered earlier.

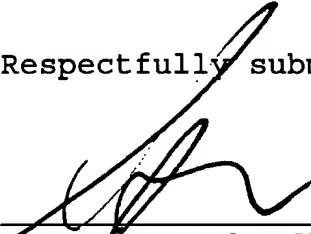
New claim 14 is an independent claim directed to the foregoing aspect in embodiments wherein an aerosol generator includes "an atomizer" which atomizes "a liquid solution of an active ingredient and a volatile solvent," as in claim 13 directed to the atomized liquid embodiment of FIG. 10. New claim 18 is an independent claim directed to the foregoing aspect in embodiments wherein a metering pocket is repeatedly reloaded, such as the microscop embodiment of FIGS. 2 and 3. New claim 20 is an independent claim directed to this aspect in the context of embodiments where there are a plurality of metering pockets sequentially presented to the location of a jet, such as the rotary metering pocket embodiment of FIG. 5 and the megadose disc embodiment of FIGS. 8 and 9. New dependent claims 17, 19 and 21 are directed to the classification aspect of the mixing/stilling/classification chamber.

There is no such disclosure or suggestion in Gerde, Riggs et al, or any other prior art of record, and claims 14-21 are accordingly allowable. Briefly, Gerde discloses what is essentially a one-shot aerosol generator. Riggs et al discloses nothing like the metering pockets, nor other aspects of applicant's invention. Neither discloses applicants' mixing/stilling/classification chamber

Conclusion

Reconsideration and allowance are requested.
Claims 9-11 have previously been indicated as allowable.
Claims 1-21 are in the case.

Respectfully submitted,

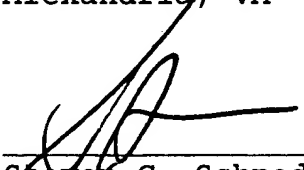


Steven C. Schnedler
Attorney, Reg. No. 27,591

Carter Schnedler & Monteith, P.A.
56 Central Avenue, Suite 101
P.O. Box 2985
Asheville, NC 28802

Telephone (828) 252-6225

I hereby certify that this paper is being deposited this date with the U.S. Postal Service as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, under the provisions of 37 CFR 1.8.



Steven C. Schnedler

APRIL 30, 2003

Date